

# PATENT COOPERATION TREATY

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### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 432722003840	<b>FOR FURTHER ACTION</b>	See Form PCT/IPEA/416
International application No. PCT/US04/36502	International filing date (day/month/year) 02 November 2004 (02.11.2004)	Priority date (day/month/year) 05 November 2003 (05.11.2003)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 35/78 and US Cl.: 424/752		
Applicant OSTEOSCREEN, INC.		

  

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
  - a. ☐ (sent to the applicant and to the International Bureau) a total of \_\_\_\_\_ sheets, as follows:
    - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - b. ☐ (sent to the International Bureau only) a total of \_\_\_\_\_ (indicate type and number of electronic carrier(s)) \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
 

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

  

Date of submission of the demand 02 September 2005 (02.09.2005)	Date of completion of this report 29 October 2005 (29.10.2005)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Randall Winston <i>J. Roberts for</i> Telephone No. 571-272-1600

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/36502

## Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☒ the description:
- pages 1-7 as originally filed/furnished
- pages\* NONE received by this Authority on \_\_\_\_\_
- pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the claims:
- pages 8 and 9 as originally filed/furnished
- pages\* NONE as amended (together with any statement) under Article 19
- pages\* NONE received by this Authority on \_\_\_\_\_
- pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the drawings:
- pages 1-4 as originally filed/furnished
- pages\* NONE received by this Authority on \_\_\_\_\_
- pages\* NONE received by this Authority on \_\_\_\_\_

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/figs NONE
- ☐ the sequence listing (*specify*): NONE
- ☐ any table(s) related to the sequence listing (*specify*): NONE

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US04/36502**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>1-15</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-15</u>	NO
Industrial Applicability (IA)	Claims <u>1-15</u>	YES
	Claims <u>NONE</u>	NO

**2. Citations and Explanations (Rule 70.7)**

Claims 1-15 lack inventive step under PCT Article 33(3) as being unpatentable over CATALFO et al (US 6,596,266). CATAFLO et al. teach (see, e.g. example 2, example 4 and example 5) the claimed method of stimulating hair growth comprising a Ginkgo bibloba that would inherently treat baldness and/or alopecia, encourage facial hair growth and inhibit protease activity of proteasomes when topically applied to the subject surface to stimulate hair growth. Cataflo et al. do not expressly teach the claimed effective amounts and the specific area to apply the topical composition. However, the adjustments of other conventional working conditions (i.e., the effective amounts and the specific area to apply the topical composition), is deemed judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claims 1-15 meet the novelty criteria set out in PCT Article 33(2) because there is no express teachings of the claimed method comprising the claimed effective amounts and the specific area to apply the topical composition.

Claims 1-15 meet the criteria set out in PCT Article 33(4), and thus claims 1-015 have industrial applicability because the subject matter claimed can be made used industry.